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EXAMINER
SCHNIZER, H

ART UNIT	PAPER NUMBER
1653	13

DATE MAILED: 01/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/060,765

Applicant(s)

Mehta et al.

Examiner

Holly Schnizer

Group Art Unit

1653



☒ Responsive to communication(s) filed on Nov 9, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 5-15, 20, 22-27, 32-38, 40-43, 67, 70, and 73 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 1, 5-14, 20, 22-27, 32-38, 40-42, 70, and 73 is/are allowed.

☒ Claim(s) 15, 43, and 67 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Status of the Claims

1. The amendment filed November 9, 1999 has been entered. Claims 2-4, 16-19, 21, 28-31, 39, 44-66, 68-69, 71-72, and 74-101 have been canceled. Therefore, Claims 1, 5-15, 20, 22-27, 32-38, 40-43, 67, 70, and 73 are pending.

Rejections Withdrawn

2. The rejection of Claims 43 and 67 under 35 U.S.C. 112, 2nd paragraph for being indefinite has been withdrawn in light of the amendment to these claims.

3. The rejection of Claims 1, 6, 7, 9, 20, 22-24, and 37 under 35 U.S.C. 102(b) as anticipated by Koke et al. is withdrawn in view of the amendment limiting the claimed vectors to those comprising "a plurality of transcription cassettes" each cassette containing a plurality of promoters.

4. The rejection of Claims 1, 6, 7, 9, 11, 12, 14, 20, 22-24, 27, 37, 41, and 65 under 35 U.S.C. 103(a) as obvious over Koke et al. in view of Ray et al. has been withdrawn in view of the amendment of Claim 1 and cancellation of Claim 65; the rejection of Claims 1, 6, 7, 9, 11, 12, 14, 20, 22-24, 37, 42, and 66 as obvious over Koke et al. in view of Craig and MacIntyre has been withdrawn in view of the amendment to claim 1 and cancellation of Claim 66; and the

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rejection of Claims 1, 5, 6, 7, 8, 9, 10, 20, 22, 23, 24, and 37 as obvious over Inouye et al. in view of Hasan and Szybalski has been withdrawn in view of the amendment of Claim 1.

New Rejections

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 15, 43, and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 15, 43, and 67 are indefinite because it is unclear what sequence is encompassed by the first 34 amino acids of parathyroid hormone since the application does not include a sequence of the parathyroid hormone. A particular protein can have varying amino acid sequences depending on the species from which it was derived. In addition, different forms of the protein with different sequences may even exist within a single species. Therefore, it is unclear what sequence is intended by "the first 34 amino acids of parathyroid hormone".

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 15, 43, and 67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. Claims 15, 43, and 67 are drawn to a vector encoding "the first 34 amino acids of parathyroid hormone". The specification, however, does not disclose even one amino acid sequence of the parathyroid hormone or a nucleic acid sequence which would encode the first 34 amino acids of parathyroid hormone. The specification fails to describe a representative species of these peptides by any identifying structural characteristics or properties. Given this lack of a representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that skilled artisan would recognize Applicants were in possession of the claimed invention.

Allowable Subject Matter

11. Claims 1, 5-14, 20, 22-27, 32-38, 40-42, 70, and 73 appear to be free of the art. Claim 1 has been amended to include the limitations of Claim 2 which the Examiner noted was allowable for the reasons cited in the previous Office Action (Paper No. 11). Claims 5-14, 20, 22-24, 27, 37, 41, 42 depend from Claim 1 and also appear to be free of the art.

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12. For reasons stated on page 9 of the previous Office Action (Paper No. 11), Claims 25, 26, 38, and 40 appear to be free of the prior art. With respect to Claim 38, it is further noted that the largest quantity of protein produced using the vectors of Koke et al. was 40-60 mg/L (page 55, column 2, last paragraph) which does not meet the limitation of "at least 100 mg/l" of Claim 38. With respect to Claim 40, the Examiner notes that Craig and MacIntyre teach the use of vectors to recombinantly express human calcitonin precursor having a C-terminal glycine. However, neither Craig and MacIntyre nor Koke et al. teach expression of salmon calcitonin precursor using the vectors and E. coli host cell strain, BLR, as in the present invention.

13. Claims 70 and 73 are free of the art for the reasons stated on page 9 of the previous Office Action (Paper No. 11).

14. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on Statement for Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 306-4119. The fax phone number for Official Papers to this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen Cochrane Carlson Ph.D

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

HS

Holly Schnizer, Ph.D.
January 20, 2000